

VDD Single Pass Pacing Leads continued

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Leads Active in Study	Qualifying Complications	Cumulative Months of Follow-Up in Study	Device Survival Probability (%)									
							Years After Implant									
							1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
5032	CapSure VDD	Mar-96	38	0	1	2,011	Survival estimate not available due to insufficient sample size									
5038	CapSure VDD-2	Sep-98	552	92	5	21,740	99.8 +0.2/-1.4	99.8 +0.2/-1.4	99.8 +0.2/-1.4	98.8 +0.8/-2.6	98.2 +1.2/-3.1	98.2 +1.2/-3.1	97.1 +1.8/-4.5	97.1 +1.8/-4.5 at 93 mo		

Source: System Longevity Study
Data as of January 31, 2009

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Implant Damage	Electrical Malfunction	Other
5032	CapSure VDD	Mar-96	5,400	1,600	24	12	0
5038	CapSure VDD-2	Sep-98	8,200	3,800	6	5	1

Source: Returned Product Analysis
Data as of January 31, 2009

Reference Chart

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
5032	CapSure VDD	Transvenous V and A Tines	Silicone	MP35N 5/6/1 Filars	Porous Platinized/ Steroid	Atr. IS-1 BI, Vent. IS-1 BI
5038	CapSure VDD-2	Transvenous Ventricular Tines	Silicone	MP35N	Porous Platinized/ Steroid	Atr. IS-1 BI, Vent. IS-1 BI